Voluntary reporting and systematic analysis of incidents in neonatal intensive care

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CHAPTER 6

Multi-centre sampling and analysis of high-risk, low-frequency incidents: lessons from 114 inotrope-related incident reports in neonatal intensive care

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Submitted

ABSTRACT

Objective: Inotropes are indispensable drugs in any intensive care unit (ICU), due to their positive effects on cardiac output in hemodynamically unstable patients. However, errors with these drugs may cause severe damage to patients. We systematically investigated the causes and severity of incidents with inotropes in neonatal ICUs (NICUs), in order to develop effective strategies to prevent future incidents with inotropes in the treatment of neonates. Moreover, we investigated whether nationwide sampling would reveal information that could not be obtained by sampling on hospital level.

Methods: Prospective multi-centre survey. Inclusion criteria: inotrope-related incidents that were reported to a voluntary, non-punitive, incident-reporting system (NEOSAFE), and that were systematically analysed using the PRISMA-Medical method. We describe the type, severity and identified causes of incidents reported from 1 July 2005 to 31 March 2007.

Results: 114 incidents with inotropes were identified from the NEOSAFE database. Although most incidents were discovered before they actually caused any injury, 54% of incidents were classified as (very) high-risk incidents. Dosing and concentration errors were frequently reported. An average of 2.4 root causes were identified on each incident analysed. Most root causes were classified as human error (66.9%). Organisational (22.5%), technical (5.5%) and patient-related (5.5%) failures accounted for the remainder of errors identified.

Conclusions: By combining data from several NICUs, we found that incidents with inotropes that occur rarely on a local level appear to have a serious impact on patient safety in the specialty of neonatology when studied nationwide. Besides human error, a great number of technical and organisational failures affect the safe use of inotropes in the NICU. Preventive strategies aimed at the whole system are therefore probably most effective. However, given the great number of human rule-based errors, we stress the need for adequate training of personnel regarding prescription and administration of inotropes.

INTRODUCTION

In the past decade, the worldwide attention for patient safety has caused a tremendous increase in research on the prevalence and types of incident in hospitals. Most patient-safety researchers agree that medication errors are the most prominent type of incident reported in hospitals.[1-5] However, although medication errors are frequently reported, there is much variability in the impact and severity of the different types of medication error.[4,6-8] In the neonatal intensive care unit (NICU), the risk for severe medication errors is thought to be higher than in the average hospital unit because of weight-based dosing, the limited compensatory abilities of the NICU population, and the frequent use of high-risk drugs such as inotropes.[9,10] Inotropes are indispensable drugs in any NICU due to their positive effects on cardiac output in hemodynamically unstable patients. However, errors in prescription, preparation or administration of these drugs may cause severe damage to patients, such as persistent hypotension when underdosing and severe hypertension when overdosing.

In the past, a punitive approach to error predominated in health care, blaming individuals for their mistakes. Currently, more and more hospitals recognise that a systematical approach is needed to analyse incident reports, investigating system deficiencies rather than investigating personal failures.[11,12] The system approach assumes that incidents are usually the result of a combination of human error as well as technical and organisational failures. In other words, a combination of several minor incidents might lead to a final (major) incident.[12] Therefore, it is thought that preventive actions aimed at the system as a whole are more effective than actions aimed at human error alone.[12]

As part of a national study on incidents in the NICU, the objective of this study was to systematically investigate the causes and severity of incidents with inotropes in the NICU, in order to develop effective strategies to prevent incidents with inotropes in the treatment of neonates in the future. Moreover, we investigated whether nationwide sampling of high-risk, low-frequency incidents would reveal information that could not be obtained by sampling on hospital level.

METHODS

Setting

A Neonatology System for Analysis and Feedback on medical Events (NEOSAFE) was implemented in eight of the ten Dutch tertiary care NICUs (14–24 beds per NICU) and one pediatric surgical ICU (14 beds, 15% neonates). In total, approximately 3500 neonates were admitted each year.

Data collection and handling

Voluntary, non-punitive incident reporting was introduced to establish specialty-based learning from incidents. Patient safety was defined as "*the avoidance and prevention of patient injuries or adverse events resulting from the process of health-care delivery*".[13] An incident was defined as "*any event which could have reduced, or did reduce the safety margin for the patient*".[14] A multidisciplinary patient-safety committee (PSC) was formed in each unit. Personnel were asked to fill in a standardised incident report form immediately after the discovery of an incident.[4,15] Incidents were either self-reported or reported by personnel who discovered the incident. The report form included a section to be filled in by the PSC during analysis, including potential severity, risk for recurrence and risk scores (Table 1). An interdisciplinary meeting provided consensus on incident categorisation and on the classification of (potential) severity. The PSCs managed an electronic database (Microsoft Access) of reported incidents and the results of the subsequent analysis, which were forwarded to the central investigator (CS) monthly. Patient and staff confidentiality were ensured by excluding personal identification from the electronic database. The local medical research ethics committee (METC, Isala Clinics, Zwolle) was consulted and it was confirmed that this study did not require approval for implementation as it only involved the registration of incidents.

Table 1. Risk scores for reported incidents*

Likelihood of recurrence	Potential consequences				
	Death	**Severe**	**Moderate**	**Minor**	**Insignificant**
Within several hours to days	4	4	3	2	2
Within several weeks	4	4	3	2	2
Within several months	4	3	3	2	1
Once every 1–5 years	4	3	2	1	1
Less than once every 5 years	3	2	2	1	1

* An interdisciplinary NEOSAFE meeting provided consensus on the classification of risk scores.
4 = extreme risk, 3 = major risk, 2 = moderate risk, 1 = minor risk.

Data analysis

Reported incidents with inotropes were systematically analysed by the local patient-safety committees, using the PRISMA-Medical method.[16-18] The main goal of PRISMA is to build a quantitative database of incidents (including near misses) and process deviations, in order to facilitate the development and evaluation of system-based preventive strategies. In the PRISMA-Medical method three main steps can be identified: (1) the Causal Tree incident description method; (2) classification of root causes by the Eindhoven Classification Model (ECM); and (3) formulation of structural measures for improvement (Classification/Action Matrix). As both active failures (human error) and latent conditions (technical and organisational failures) of incidents are systematically considered with the PRISMA-Medical method, the results of this analysis can be used to provide a more realistic view of how the system actually works.[11,18] Each PRISMA-analysis was conducted by two members of the committee, who were familiar with the department and its processes, and PRISMA-trained with substantial interrater reliability regarding the classification of root causes (κ value 0.58–0.61).[19] Committees were encouraged to analyse incidents within 2 weeks after reporting. We describe the type, severity and identified causes of inotrope-related incidents reported and systematically analysed from 1 July 2005 to 31 March 2007.

RESULTS

Figure 1 shows the selection process. During the study period, 114 incidents with inotropes were identified from the NEOSAFE database. Incidents took place at different stages of the medication-use process (Figure 2).[8] Severe injury was not reported, although in 26 incidents the level of injury was not known. Moderate injury was reported in one incident (persistent hypotension due to leaking of parenteral nutrition into a second lumen containing dopamine). Although most incidents were discovered before they actually caused any injury, 54% of incidents were classified as (very) high-risk incidents (score 3 or 4, Table 1).

Dosing and concentration errors were frequently reported. The most prominent error of this type was a 60-fold dosing error of isoprenaline, which is prescribed per hour in contrast to most other inotropes which are prescribed per minute. Other errors frequently occurred during dose adjustments, when calculation errors in the preparation of different concentrations were often reported. Several reports concerned the flushing

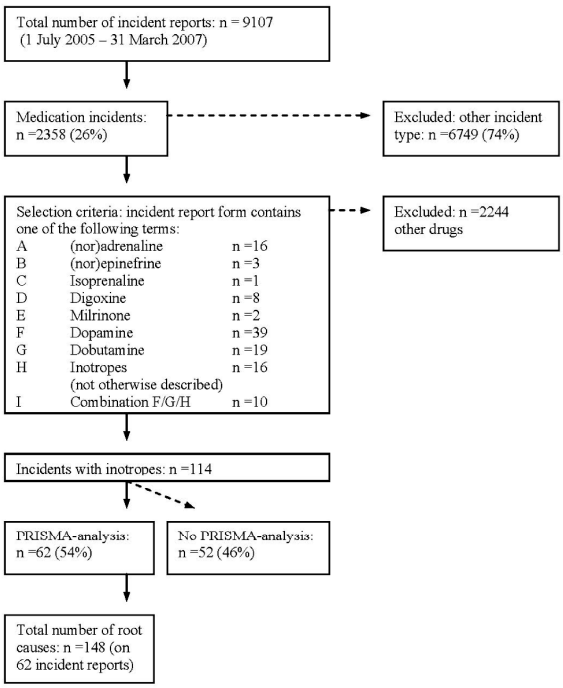

Figure 1. Selection of incident reports.

of inotropes when administering another drug to the wrong lumen, or an overdose of inotropes when increasing the infusion rate of the wrong lumen in a double-lumen catheter. Failure of the infusion pump, such as a battery defect, was another reported cause of error. Errors in route of administration concerned i.e. the absence of a filter when administering dopamine and dobutamine.

Fifty-four percent of all reported incidents with inotropes were systematically analysed using the PRISMA-Medical methodology. On average, 2.4 root causes were identified on each incident analysed (variation between incident reports: 1–6 root cause). Most root causes were classified as human error (66.9%). Organisational (22.5%), technical (5.5%) and patient-related (5.5%) failures accounted for the remainder of failures identified. Table 2 shows the distribution of root causes according to the ECM, and proposed actions to prevent their recurrence.

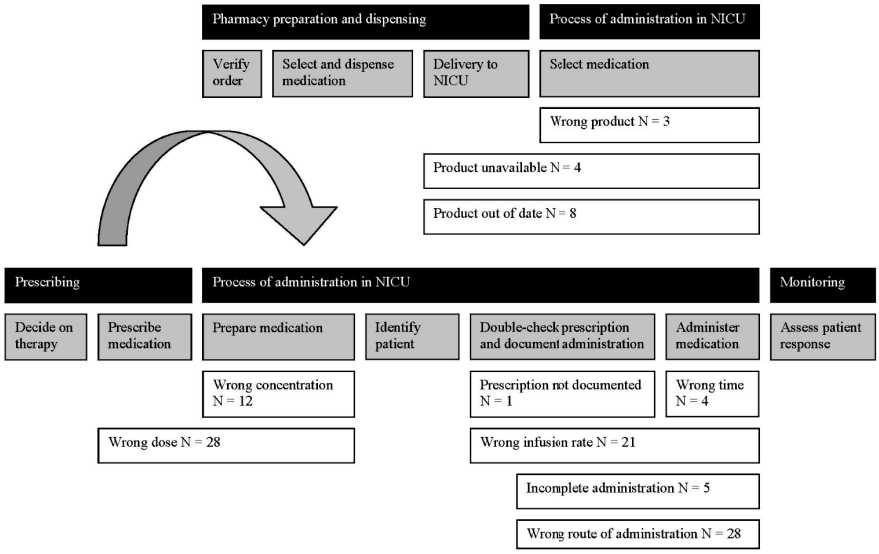

Figure 2. Failures with inotropes as identified in each step of the medication use process (n = 114).

Table 2. Results of systematic analysis of 62 incidents on inotropic agents

Classification code[a]		Category	N[b]	Preventive actions[c]
Technical	T-EX	external	2	Escalation[d]
	TD	design	2	Technology / equipment
	TC	construction	4	Technology / equipment
	TM	materials	0	Technology / equipment
Organisational	O-EX	external	2	Escalation
	OK	transfer of knowledge	4	Escalation
	OP	protocols	6	Procedures
	OM	management priorities	6	Escalation
	OC	culture	11	Reflection
Human	H-EX	external	1	Escalation
	HKK	knowledge-based behaviour	9	Information & communication (NO MOTIVATION)
	HR	rule-based behaviour	87	Training
	HS	skill-based behaviour	5	Technology / equipment (NO MOTIVATION)
Other factors	PRF	patient-related factor	8	
	X	unclassifiable	2	
Total			**148**	

[a] According to the PRISMA-Medical Eindhoven Classification Model.
[b] Number of identified root causes.
[c] As proposed by the PRISMA-Medical Classification / Action Matrix.
[d] Handling the problems at a higher organisational level.

DISCUSSION

This study shows that incidents with inotropes are a serious hazard to patients in the NICU. By combining data from several NICUs, we found that incidents with inotropes that occur rarely on a local level appear to have a serious impact on patient safety in the specialty of neonatology when studied nationwide. This finding shows that sampling of reports on high-risk, low-frequency incidents at a national level yields valuable information that cannot be found by sampling at single hospital level. Besides human error, a great number of technical and organisational failures affect the safe use of inotropes in the NICU. This supports the theory of the system approach, which assumes that incidents are usually the result of a combination of human error as well as technical and organisational failures.

Failures in organisational culture as well as management priorities contributed to a substantial number of incidents with inotropes (Table 2). With respect to the former problem, the current manner in which NICU personnel deals with safety should be evaluated in the presence of NICU management, whereas the latter problem (management priorities) should be handled at a higher organisational level ('escalation').

However, despite the significant number of technical and organisational failures, the majority of incidents were still due to human error. Given the great number of human rule-based errors, we stress the need for adequate training of personnel; such as instructing doctors how to prescribe, and practicing dose calculation and administration.[20] Also, increased attention to information and communication is recommended to prevent knowledge-based errors.[21] In this respect, we emphasise that motivation of personnel only is an ineffective method in the prevention of human error, as described in previous research.[16-18] Moreover, it is important to be aware of the limits of human performance and the need to make system changes to accommodate these limits.[12,22] Therefore, we recommend specific interventions with respect to the high incidence of dosing errors. First, uniform prescription of inotropes (for instance, dosage per minute) might contribute to the prevention of prescription and calculation errors, like 60-fold dosing errors.[23,24] Second, information technology such as computed physician-order entry might contribute to a decrease in calculation errors.[25,26] Third, a specialised NICU pharmacist might contribute to a quicker detection of prescription or preparation errors and thus to the prevention of injury.[27,28] However, more research is needed to find more evidence for the effectiveness of this intervention.[29]

This study has some limitations. Several units reported a lack of time to handle the large number of incidents reported after the introduction of the voluntary reporting system. As a result, only 54% of all eligible reported incidents were analysed using the PRISMA-Medical methodology. Although the units that expected time-management problems were instructed well in time to analyse every third report so as to get a representative sample of PRISMA-analyses, selective analysis may have affected the final profile of root causes.

The percentage of human error in our study (67%) was rather high compared to a study on reported incidents in transfusion medicine (46%),[30] and compared to a study on incidents reported to The Netherlands Health Care Inspectorate (42%),[31] both using PRISMA-analysis. This may reflect the actual situation in the NICU, where several vital functions have to be monitored or supported simultaneously, which strongly depends on human actions. However, it may also be due to 'person-oriented' biases during the PRISMA-analysis.[19] If the latter is the case, one should expect to observe a decrease in the percentage of human error after repeated education. Although we did not find a decrease during the study period, this remains an important issue for further studies.

CONCLUSION

Incidents with inotropic agents have a serious impact on patient safety in neonatology when studied nationwide. Besides human error, a great number of technical and organisational failures affect the safe use of inotropes in the NICU. Preventive strategies aimed at the whole system are therefore probably most effective. However, given the great number of human rule-based errors, we stress the need for adequate training of personnel regarding prescription and administration of inotropes.

REFERENCES

1. Kaushal R, Bates DW, Landrigan C et al. Medication errors and adverse drug events in pediatric inpatients. *JAMA* 2001;285:2114−20.
2. Bates DW, Cullen DJ, Laird N et al. Incidence of adverse drug events and potential adverse drug events: implications for prevention. ADE Prevention Study Group. *JAMA* 1995;274:29−34.
3. Snijders C, van Lingen RA, Molendijk A, Fetter WP. Incidents and errors in neonatal intensive care: A review of the literature. *Arch Dis Child Fetal Neonatal Ed* 2007;92:391−8. Epub 2007 Mar 21.
4. Snijders C, van Lingen RA, Fetter WP, van der Schaaf TW, Molendijk A. Specialty-based, voluntary incident reporting in neonatal intensive care: description of 4846 incident reports. *Arch Dis Child Fetal Neonatal Ed* 2009;94:210−5. Epub 2008 Oct 6.
5. Suresh G, Horbar JD, Plsek P et al. Voluntary anonymous reporting of medical errors for neonatal intensive care. *Pediatrics* 2004;113:1609−18.
6. Fortescue EB, Kaushal R, Landrigan CP et al. Prioritizing strategies for preventing medication errors and adverse drug events in pediatric inpatients. *Pediatrics* 2003;111:722−9.
7. Leape LL, Bates DW, Cullen DJ et al. Systems analysis of adverse drug events. ADE Prevention Study Group. *JAMA* 1995;274:35−43.
8. Kunac DL, Reith DM. Identification of priorities for medication safety in neonatal intensive care. *Drug Saf* 2005;28:251−61.
9. Simpson JH, Lynch R, Grant J, Alroomi L. Reducing medication errors in the neonatal intensive care unit. *Arch Dis Child Fetal Neonatal Ed* 2004;89:480−2.
10. Weingart SN, Wilson RM, Gibberd RW, Harrison B. Epidemiology of medical error. *BMJ* 2000;320:774−7.
11. Leape LL. Reporting of adverse events. *N Engl J Med* 2002;347:1633−8.
12. Reason J. Human error: models and management. *BMJ* 2000;320:768−70.
13, Sorra JS, Nieva VF. Hospital Survey on Patient Safety Culture. (Prepared by Westat, under Contract No. 290-9609994). AHRQ Publication No. 04-0041. Rockville MD: Agency for Healthcare Research and Quality, 2004.
14. Beckmann U, Baldwin I, Hart GK, Runciman WB. The Australian Incident Monitoring Study in Intensive Care: AIMS-ICU. An analysis of the first year of reporting. *Anaesth Intensive Care* 1996;24:320−9.
15. Aspden PH, Corrigan JM, Wolcott J. Patient safety: achieving a new standard for care. Washington DC, National Academy Press, 2004.
16. Van der Schaaf TW. Near miss reporting in the chemical process industry. Eindhoven, The Netherlands: Eindhoven University of Technology, 1992, Thesis.
17. Battles JB, Kaplan HS, Van der Schaaf TW, Shea CE. The attributes of medical event-reporting systems. Experience with a prototype medical event-reporting system for transfusion medicine. *Arch Pathol Lab Med* 1998;122:231−8.
18. Van der Schaaf TW, Habraken MMP. PRISMA-Medical: a brief description. Eindhoven University of Technology, 2005. Available at: http://www.who.int/patientsafety/taxonomy/PRISMA_Medical.pdf (Accessed 19 March 2009).

19. Snijders C, van der Schaaf TW, Klip H, van Lingen RA, Fetter WPF, Molendijk A. Feasibility and reliability of PRISMA-medical for specialty-based incident analysis. *Qual Saf Health Care* 2009;18:486−91.
20. Leonard MS, Cimino M, Shaha S, McDougal S, Pilliod J, Brodsky L. Risk reduction for adverse drug events through sequential implementation of patient safety initiatives in a children's hospital. *Pediatrics* 2006;118:e1124−9.
21. Prizzi L, Goldfarb NI, Nash DB. Crew resource management and its applications in medicine. In: Making healthcare safer. Rockville MD, Agency for Healthcare Research and Quality, 2002.
22. Schneider PJ. Applying human factors in improving medication-use safety. *Am J Health Syst Pharm* 2002;59:1155−9.
23. Chappell K, Newman C. Potential tenfold drug overdoses on a neonatal unit. *Arch Dis Child Fetal Neonatal Ed* 2004;89:483−4.
24. Larsen GY, Parker HB, Cash J, O'Connell M, Grant MC. Standard drug concentrations and smart-pump technology reduce continuous-medication-infusion errors in pediatric patients. *Pediatrics* 2005;116:e21−5.
25. Bates DW, Gawande AA. Improving safety with information technology. *N Engl J Med* 2003;348:2526−34.
26. Cordero L, Kuehn L, Kumar RR, Mekhjian HS. Impact of computerized physician order entry on clinical practice in a newborn intensive care unit. *J Perinatol* 2004;24:88−93.
27. Leape LL, Cullen DJ, Clapp MD et al. Pharmacist participation on physician rounds and adverse drug events in the intensive care unit. *JAMA* 1999;281:267−70.
28. Campino A, Lopez-Herrera MC, Lopez-de-Heredia I, Valls-I-Soler A. Medication errors in a neonatal intensive care unit. Influence of observation on the error rate. *Acta Paediatr* 2008;97:1591−4.
29. Chedoe I, Molendijk HA, Dittrich ST et al. Incidence and nature of medication errors in neonatal intensive care with strategies to improve safety: a review of the current literature. *Drug Saf* 2007;30:503−13.
30. Kaplan HS, Battles JB, Van der Schaaf TW, Shea CE, Mercer SQ. Identification and classification of the causes of events in transfusion medicine. *Transfusion* 1998;38:1071−81.
31. Habraken MMP. [Better analysis of incidents: PRISMA-method improves Inspectorate's knowledge of medical mishaps]. *Medisch Contact* 2005;22:940−3 (Dutch).